GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2251
ANSWERED ON:28.07.2017
Law Regulating Diagnostic Labs
Singh Shri Sunil Kumar

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether there is any law to regulate diagnostic labs for their services, pricing and quality;

(b) if so, the details thereof; and

(c) the corrective measures taken by the Government in this regard?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SMT. ANUPRIYA PATEL)
(a) & (b): Health is a State subject and regulation of diagnostic laboratories falls within the domain of State Governments. The Government of India has, however, enacted the Clinical Establishments (Registration and Regulation) Act, 2010 and notified Clinical Establishments (Central Government) Rules, 2012 for registration and regulation of Clinical Establishments, including Diagnostic Laboratories. The Act is currently applicable in ten States and all Union Territories except Delhi. In the State /UTs where the said Act is in force, the clinical establishments are required to meet the norms such as minimum standards of facilities and services, minimum requirement of personnel, maintenance of records and reports and displaying of rates at a conspicuous place.

The clinical establishments are also required to follow Standard Treatment Guidelines issued by the Central/State Governments and charge rates for each type of procedure and service within the range of rates determined from time to time. The National Council for Clinical Establishments has approved a standard list of medical procedures and a standard template for costing medical procedures and shared the same with the States and Union Territories. Further action lies within the purview of the State/UT Governments.

(c): Does not arise.